

JAN 3 0 2002

K012184 p1/2
Premarket Notification
Blackstone Medical, Inc.
Blackstone™ III° Anterior Cervical Plating System
Confidential

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Firm: Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, MA 01104

510(k) Contact: Alan Lombardo
Director of Engineering

Trade Name: Blackstone™ III° Anterior Cervical Plating System

Common Name: Cervical Plating Instrumentation

**Device Product Code
& Classification:** KWQ 888.3060 - Spinal Intervertebral Body Fixation
Orthosis

Substantially

Equivalent Devices:

Aesculap® ABC Cervical Plating System (K000486)
Blackstone™ Anterior Cervical Plate System (K974885)
Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System
(K971883)
Danek ZEPHIR™ Anterior Cervical Plate System (K994239)

Device Description:

The Blackstone™ III° Anterior Cervical Plating System is a titanium alloy; multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build an anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation, which assists in the surgical implantation of the devices.

Intended Use / Indications for Use:

Blackstone™ III° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

- a) degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) spondylolisthesis;
- c) fracture;
- d) spinal stenosis;
- e) deformities (i.e., scoliosis, kyphosis, and/or lordosis);

- f) tumor;
- g) pseudarthrosis;
- h) revision of previous surgery

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Blackstone™ III° Anterior Cervical Plating System by its very nature is substantially equivalent to the predicate devices listed below:

Aesculap® ABC Cervical Plating System (K000486)
Blackstone™ Anterior Cervical Plate System (K974885)
Synthes Spine Small Stature Anterior Cervical Vertebrae Plate System
(K971883)
Danek ZEPHIR™ Anterior Cervical Plate System (K994239)

The FDA has cleared each of these devices, for anterior fixation to the cervical spine from C2 to C7.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 30 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan Lombardo
Director Engineering
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K012184
Device/Trade Name: Blackstone™ III◦ Anterior Cervical Plating System
Regulatory Number: 21 CFR 888.3060
Regulatory Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 10, 2001
Received: June 12, 2001

Dear Mr. Lombardo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

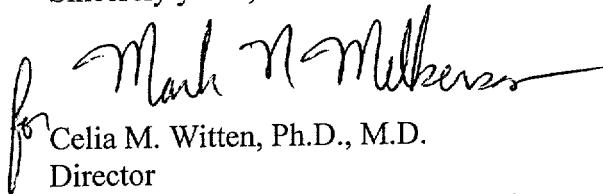
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Alan Lombardo

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Milbrink

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number: K012184

Device Name: Blackstone™ III° Anterior Cervical Plating System

Indications for Use:

Blackstone™ III° Anterior Cervical Plating System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

- a) degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
- b) spondylolisthesis;
- c) fracture;
- d) spinal stenosis;
- e) deformities (i.e., scoliosis, kyphosis, and/or lordosis);
- f) tumor;
- g) pseudarthrosis;
- h) revision of previous surgery

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkers
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012184